Applicant Details

First Name Anne
Last Name Bigler

Citizenship Status U. S. Citizen

Email Address <u>bigleranne@gmail.com</u>

Address Address

Street

48 W 87 St, #1B

City New York State/Territory New York

Zip 10024

Contact Phone Number 3028248248

Applicant Education

BA/BS From Boston College
Date of BA/BS May 2018

JD/LLB From University of Virginia School

of Law

http://www.law.virginia.edu

Date of JD/LLB May 23, 2021

Class Rank School does not rank

Does the law school have a Law

Review/Journal?

Law Review/Journal

Moot Court Experience

No

Bar Admission

Admission(s) New York

Prior Judicial Experience

Judicial Internships/Externships No
Post-graduate Judicial Law Clerk No

Specialized Work Experience

Recommenders

Russell, Capone rcapone@cooley.com
Gilbert, Michael mgilbert@law.virginia.edu
434-243-8551
Doran, Michael mdoran@law.virginia.edu
(434) 924-6331
Flath, Nicholas nflath@gmail.com

This applicant has certified that all data entered in this profile and any application documents are true and correct.

Anne Elizabeth Bigler 48 W 87 St., Apt. #1B New York, NY 10024 (302) 824-8248

May 10, 2023

The Honorable Maryellen Noreika United States District Court District of Delaware J. Caleb Boggs Federal Building 844 N. King Street Wilmington, DE 19801-3555

Dear Judge Noreika:

I am a second-year Litigation associate at Cooley LLP, and I write to apply for a clerkship in your chambers for the 2024-2025 term. I was born and raised in the Philadelphia/Wilmington area just north of the Delaware border, first in Boothwyn and then in West Chester. I am a graduate of Unionville High School in Kennett Square and have previously worked in Wilmington. At Cooley, technology, science, and biopharmaceuticals have played a substantial role in my cases.

I have enclosed my resume, list of references, law school transcript, undergraduate transcript, and a writing sample. You will also receive letters of recommendation from Vice Dean Michael Gilbert and Professor Michael Doran, as well as from colleagues Russell Capone and Nicholas Flath. I am happy to provide any further information that you require.

Thank you for your consideration. I look forward to hearing from you.

Respectfully,

Anne E. Bigler

Anne E. Bigler

| (302) 824-8248 | bigleranne@gmail.com | 48 W 87th St., Apt. #1B, New York, NY 10024

EDUCATION

University of Virginia School of Law, Charlottesville, VA J.D., May 2021

- Virginia Journal of International Law, Publications Editor
- Feminist Legal Forum, Treasurer
- Virginia Innocence Project Pro Bono Clinic, Volunteer

Boston College, Chestnut Hill, MA

B.A., Political Science (Minor: Management & Leadership), summa cum laude, May 2018

- Phi Beta Kappa
- Thesis: "Hindering the Homeless?: Examining the Sources and Practical Implications of Fragmentation in the Homelessness Policy Area"

EXPERIENCE

Cooley LLP, New York, NY

Associate, October 2021 – present

- Drafted complaint and motions including motions to dismiss and motions in *limine*
- Drafted memoranda on legal issues including a memorandum on the False Claims Act in the customs context
- Interviewed witness in an internal investigation of fraud at a public company
- Assisted in trial preparation by preparing witness examination outlines and maintaining exhibit list
- Researched legal questions including the preclusive effect of arbitration awards entered into judgment by a court of another state
- Managed document review and production process in civil litigation
- Developed partner presentation to the Department of Justice in white collar matter

The Legal Aid Society, Queens, NY

Intern, Criminal Defense Practice, May – August 2019

- Drafted motions for cases at different stages of the litigation process, including motions to dismiss for facial insufficiency and based on the speedy trial law
- Conducted client interviews at arraignments and used the content of those interviews to make oral arguments before a judge on why bail should not be set and to negotiate with ADAs to reach a disposition favorable to our clients
- Researched pertinent legal questions and drafted memos that clearly and concisely articulated how relevant statutes have been interpreted

Collins & Associates Attorneys, Wilmington, DE *Intern, Criminal Defense Office*, May – August 2018

- Analyzed and drafted summaries of witness statements and prepared memoranda with recommendations regarding beneficial and problematic witnesses
- Reviewed case files and trial transcripts to identify cases eligible for post-conviction relief

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List of References

Michael Gilbert*

Vice Dean University of Virginia School of Law (434) 243-8551 mgilbert@law.virginia.edu Dean Gilbert taught my Legislation, Election Law, and Law of Corruption classes during law school.

Michael Doran*

Professor of Law University of Virginia School of Law (434) 924-6331 mdoran@law.virginia.edu Professor Doran taught my Trusts & Estates and Native American Law classes during law school.

Russell Capone*

Partner, Cooley LLP (212) 479-6580 rcapone@cooley.com

I worked with Russell on a False Claims Act matter where I was the only associate.

Bill Schwartz

Senior Counsel, Cooley LLP (212) 479-6290 wschwartz@cooley.com

I went to trial with Bill in February 2023 in a judgment enforcement proceeding seeking turnover on the basis of an alleged fraudulent conveyance.

Nicholas Flath*

Special Counsel, Cooley LLP (212) 479-6511 nflath@cooley.com

I went to trial with Nick in February 2023 in a judgment enforcement proceeding seeking turnover on the basis of an alleged fraudulent conveyance.

Ian Shapiro

Director, Partner, Cooley LLP (212) 479-6441 ishapiro@cooley.com

Ian is a colleague and mentor. We worked together on a bankruptcy trial.

Victoria Pasculli

Associate, Cooley LLP (212) 479-6879 vpasculli@cooley.com

Victoria is a colleague and mentor. We worked together on a False Claims Act case and a mortgage-related class action case.

Alan Levine

Senior Counsel (212) 479-6260 alevine@cooley.com Alan is a friend and mentor. We worked together on the Charlottesville litigation under the Klan statute against "Unite the Right" rally participants.

^{*} Will provide written letter of recommendation.

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Page 1 of 1



BOSTON COLLEGE

Office of Student Services Academic Transcript

Boston College Office of Student Services Lyons Hall 103 140 Commonwealth Avenue Chestnut Hill, MA 02467

NAME: ANNE ELIZABETH BIGLER STUDENT ID#: 74815560 SCHOOL: MORRISSEY COLLEGE OF ARTS AND SCIENCES DATE PRINTED: 04/18/2023 DEGREE: BACHELOR OF ARTS 05/21/2018 SUMMA CUM LAUDE MAJOR: POLITICAL SCIENCE MINOR: MANAGEMENT AND LEADERSHIP PAGE: 1 OF 2 DISTINCTION: PHI BETA KAPPA, COMPLETED ARTS & SCIENCES HONORS PROGRAM SPRING 2016 ARTS & SCIENCES ADVANCED PLACEMENT HONR1203 WESTRN CULTURL TRAD VII 03 A BIOL1001 BIOLOGY CORE EOUIV HONR1204 WESTRN CULTURL TRAD VIII 03 A ENGL1004 ENGLISH CORE EOV: WRITING ENGL1005 ENG CORE EQVIV:LITERATURE MGMT1021 ORGANIZATIONAL BEHAVIOR 03 A 03 A-MGMT2127 LEADERSHIP ARTH1001 FINE ARTS CORE EQUIV POLI2415 MODELS OF POLITICS 03 A-HSXX1076 AMERICAN HISTORY EQUIV EARNED CREDITS: 15 MATH1011 MATH CALCULUS CORE EQUI GPA: 3.868 FALL 2016 ARTS & SCIENCES LANGUAGE PROFICIENCY UNIV COLLEGE LONDON (ENGLAND) LANG PROFICIENCY-COMPLETE FALL 2014 ARTS & SCIENCES UXSA1025 19-20TH CEN ART IN LONDON 04 A ENGL2170 INTRO TO BRIT LIT&CULTURE 03 UXSA1039 BRITISH HIST 1689-1860 04 A-HONR1101 WESTRN CULTURL TRAD I UXSA1057 BRITISH POLITICS 04 A-UXSA1057 POLITICS OF EURO UNION 04 A-HONR1102 WESTRN CULTURL TRAD II 03 A HIST1011 ATLANTIC WORLDS I 03 A EARNED CREDITS: 16 SPRING 2017 ARTS & SCIENCES PSYC1111 INTRO/PSY AS SOC SCIENCE 03 HONR3302 HON SEM: 20THC/TRDTN II EARNED CREDITS: 15 GPA: 3.868 SPRING 2015 ARTS & SCIENCES MGMT2111 ETHICAL LEADERSHIP SKILLS 03 A-HONR1103 WESTRN CULTURL TRAD III POLI2301 POLICY&POLITICS IN U.S. 03 A HONR1104 WESTRN CULTURL TRAD IV 03 POLI2536 NONSTATE ACTORS/WRLD POLI 03 A HIST1012 ATLANTIC WORLDS II POLI2626 SHAKESPEARE'S POLITICS 03 A POLI1041 FUND/CONCEPTS OF POLITICS 03 EARNED CREDITS: 15 GPA: 3.868 PSYC1110 INTRO/PSY AS NAT SCIENCE 03 ARTS & SCIENCES FALL 2017 EARNED CREDITS: 15 GPA: 4.000 AADS3310 RACE, LAW&RESISTANCE 03 A-MGMT2132 MANAGING CHANGE FALL 2015 ARTS & SCIENCES 03 A-HONR1201 WESTRN CULTURL TRAD V 03 A BSLW1147 CONSTITUTIONAL LAW 03 A HONR1202 WESTRN CULTURL TRAD VI 03 A 03 A-POLI4961 HONORS THESIS TCSP1199 ISLAMIC CIVILIZATION POLI4933 HONORS SEMINAR 03 A 03 03 EARNED CREDITS: 15 POLITIO91 INTRO TO COMPARATIVE POL -----CONTINUED NEXT PAGE-----POLI2360 SEM:RIGHTS IN CONFLICT 0.3 GPA: 4.000 EARNED CREDITS: 15 -----END OF COLUMN-----

ISSUED TO:

ANNE ELIZABETH BIGLER 1035 Ballintree Ln West Chester PA 19382 Bryan D. Jones
University Registrar

BOSTON COLLEGE

Office of Student Services Academic Transcript

Boston College Office of Student Services Lyons Hall 103 140 Commonwealth Avenue Chestnut Hill, MA 02467

STUDENT ID#: 74815560

DATE PRINTED: 04/18/2023

NAME: ANNE ELIZABETH BIGLER

SCHOOL: MORRISSEY COLLEGE OF ARTS AND SCIENCES

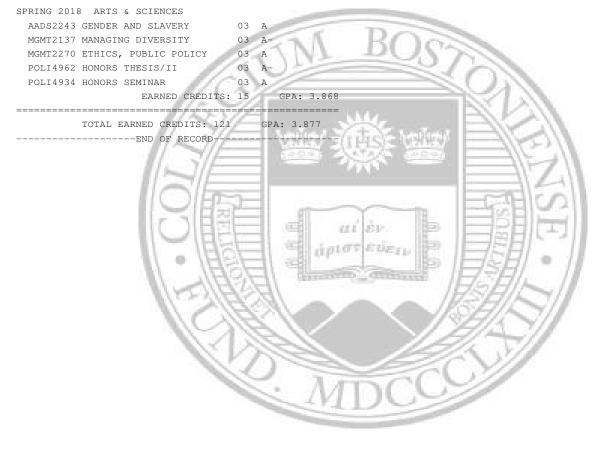
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PAGE: 2 OF 2



ISSUED TO:

ANNE ELIZABETH BIGLER 1035 Ballintree Ln West Chester PA 19382 Bryan D. Jones
University Registrar

Cooley

Russell Capone T: +1 212 479 6580 RCapone@cooley.com

Your Honor:

I write to convey my unequivocal recommendation in support of Anne Bigler's application for a clerkship. I have worked closely with Anne over the course of the last year and, as a result, am confident that she would be a tremendous asset to your chambers.

I have been a partner in the White Collar and Investigations Group at Cooley since July 2021. Prior to that point, I spent more than a decade at the U.S. Attorney's Office for the Southern District of New York, including as Chief of the SDNY's Public Corruption Unit and as Chief Counsel to then-U.S. Attorney Audrey Strauss. At Cooley, I represent individuals and companies in government and internal investigations, as well as companies in commercial litigation.

Over the last year, Anne has worked with me on two government investigations into potential violations of the False Claims Act: one involving alleged violations of U.S. customs laws, and one involving alleged overbilling to Medicare and Medicaid for the use of a particular medical device. Anne's work has ranged from legal research, to drafting memos, to reviewing and analyzing key documents, to assisting in witness interviews, to interacting directly with the clients.

My work with Anne confirms that she is extremely talented on all of the axes that are important to the role of a clerk. She is a highly effective researcher and writer. She is a team player who earns the like and respect of her colleagues. And she demonstrates intelligence and judgment beyond her experience. In fact, it was Anne's research abilities on the first matter – involving the standards for bringing "reverse" false claims actions and analogizing existing cases to our own matter involving customs laws – that led me to seek her out for the second. In the second matter, Anne was the sole associate in our representation of the medical device company's co-founder. She provided equally impressive research and writing, with incredible efficiency despite being the only associate on the matter. I was also impressed with Anne's ability to juggle assignments from multiple associates and partners on various matters and manage her time effectively – a skill that many associates take much longer to develop.

While the first matter is ongoing, the second matter has largely concluded. Anne played an outsized role in putting together our substantive advocacy before the Department of Justice, including an effective PowerPoint presentation and talking points. Ultimately, while reaching a settlement with the Company and other executives, the Department made the decision *not* to intervene as to our client, in no small part thanks to Anne's hard work on the matter.

In addition, it bears noting that since she began at the Firm during the COVID pandemic, Anne has regularly been coming into the office multiple times a week, including during earlier phases when most of her associate colleagues were not. She has demonstrated an eagerness to substantively ingrain herself in her matters and get to know her colleagues around the firm. She is a pleasure to work with and be around – genuinely friendly, outgoing, and supportive of her colleagues. I have no doubt that she would be an excellent citizen of Your Honors' chambers.

Cooley LLP 55 Hudson Yards New York, NY 10001-2157 t: +1 212 479 6000 f: +1 212 479 6275 cooley.com

Cooley

September 2, 2022 Page Two

This year, I was responsible for compiling and delivering Anne's review. As a result, I can say that the commentary I am providing here is not only my own; it is shared universally by the senior associates and partners with whom Anne has worked. The partners in our New York litigation department easily reached a consensus that Anne was the highest performing associate for her class year, and all continue to seek her out for their cases.

I recommend Anne to you with much enthusiasm and without reservation. I would be happy to speak directly if you would find it helpful to do so.

Russell Capone

May 11, 2023

The Honorable Maryellen Noreika J. Caleb Boggs Federal Building 844 North King Street, Room 4324 Wilmington, DE 19801-3519

Dear Judge Noreika:

I am writing to recommend enthusiastically Anne Bigler, a 2021 graduate of UVA Law School, for a clerkship in your chambers. Anne is very smart, determined, and personable. She compares favorably to other students of mine who have clerked for federal and state judges and has my strong recommendation.

Anne took three courses from me: Legislation (103 students), Regulation of the Political Process (86 students), and the Law of Corruption (16 students). The first two were lectures focused on doctrine: the canons of construction, the Voting Rights Act, campaign finance, and so on. The third was a discussion-based seminar that covered topics such as bribery, honest services fraud, and the Emoluments Clauses. Anne performed very well in all three settings, impressing me and her fellow students with her engagement and sharp insights. She is a clear thinker, a talented writer, and a composed speaker.

Separate from academics, Anne was a model of engagement at UVA Law, serving as an editor on a distinguished journal, assuming leadership roles in the Feminist Legal Forum, and volunteering for pro bono projects. Much of this is apparent in Anne's resume. What the resume does not show is her personal side. I got to know Anne well during her time here, and I know her to be unfailingly friendly, interesting, and professional. It was a pleasure to have her at UVA, and I am confident she would make an excellent clerk.

Sincerely,

Michael Gilbert

May 16, 2023

The Honorable Maryellen Noreika J. Caleb Boggs Federal Building 844 North King Street, Room 4324 Wilmington, DE 19801-3519

Dear Judge Noreika:

I am writing to recommend Anne Bigler for a clerkship in your chambers. Anne was an excellent law student, and I am confident that she would be a successful law clerk. I recommend her highly, and I respectfully urge you to give her serious consideration.

Anne was a strong student at the University of Virginia School of Law. Her grade point average of 3.44 placed her near the middle of the Class of 2021, and as shown by her transcript, her grades improved steadily as she found her footing. I believe that the predominance of "A" grades in her third year of studies best reflects Anne's abilities.

Anne was in two of my courses: Trusts & Estates (Spring of 2020) and Native American Law (Spring of 2021). Unfortunately, the onset of the public-health crisis in 2020 pushed the Law School onto a strict pass-fail grading system for the Spring term, and I cannot really comment on Anne's work in Trusts & Estates. However, Anne impressed me in Native American Law the following year. She earned an "A-" grade in that course, which is dominated by complicated questions of civil and criminal jurisdiction, sovereign immunity, statutory and treaty interpretation, and Constitutional law.

I have had several occasions to speak with Anne outside class, and I have found her to be just as impressive as her coursework indicates. Anne is intelligent and conscientious. She has strong analytic abilities, and she is confident and patient when faced with new challenges. Anne is also a very pleasant individual, and I am sure that she would contribute to a collegial atmosphere in chambers.

Anne's achievements were not limited to the classroom. She was active in student groups at the Law School, including the Feminist Legal Forum and the Virginia Innocence Project, and she was on the editorial board of the Virginia Journal of International Law. And of course, Anne has gained valuable experience since graduation as a litigation associate at Cooley LLP in New York.

I hold Anne in high regard. I have no doubt that she would serve you well as a law clerk, and I urge you not to pass on her application.

Sincerely,

/s/

Michael Doran Albert V. Bryan Jr. '50 Research Professor of Law University of Virginia School of Law 580 Massie Road Charlottesville, Virginia 22903 Phone: 434-924-6331 Fax: 434-982-2845

Email: mdoran@law.virginia.edu

Nicholas Flath

nflath@gmail.com 347-306-0567 2448 Benson Ave., Apt. 1 Brooklyn, NY 11214

April 28, 2023

Re: Clerkship Recommendation For Anne Bigler

Dear Sir or Madam:

I am a special counsel in the litigation department of Cooley LLP's New York office. I have been practicing law for over a decade at Cooley and have worked with many talented and hard-working associates. Anne is one of our best, and I recommend her as a clerkship candidate.

In August 2022, one of our colleagues left the firm. He had been the associate responsible for managing one of Cooley's longstanding matters - *Uni-Rty v. NYGFI*, NY Cty. # 157621-2012, in which Cooley represented the "Chu" respondents. The complexity of the "Chu" case was legendary in the department, and speculation was rife as to who would have the unenviable burden of learning the record and taking the case to trial.

As luck would have it, Anne and I drew the short straw. We had a daunting task. Cooley had been defending the case for a decade. It was a judgment enforcement proceeding, and the underlying judgment had itself been entered in a federal case that had been first filed in 1995, relating to real estate transactions dating back to the early 1990s. The record was massive, including over a hundred depositions comprising thousands of pages of prior testimony by our clients and their agents, as well as hundreds of potentially important documents. Anne and I had only two months to prepare the case for trial, set for October 2022.

Within weeks, Anne and I had read the depositions, prepared our exhibit list, and begun preparing witness outlines. At the same time, Anne conducted research to bulk up our defenses to the Petitioners' complex claims under the New York Debtor Creditor Law. Throughout this intense period, Anne juggled her other active matters with grace and skill. At the last moment before trial, the judge (Justice Ramseur) ordered a continuance and set a schedule for the orderly exchange of exhibits and deposition designations. Once we received Plaintiffs' exhibit list and deposition designations, Anne and I drafted objections, prepared for and handled the meet-and-confer, and briefed a motion *in limine* in which we asked Justice Ramseur to exclude dozens of objectionable exhibits. Anne did all of this while also serving as a core team member on several other active litigations and white-collar investigations.

In February 2023, just a few weeks ago, we took the case to trial. Anne was instrumental in preparing our witnesses for their testimony, managing trial logistics, and keeping everything running smoothly. I can't speak highly enough of Anne's familiarity with the record, organization, responsiveness, and good cheer during a period of intense work. During our argument on the motion *in*

limine on the first day of trial, Justice Ramseur specifically complimented Anne on the charts she had prepared which we submitted in support of our motion, and which succinctly explained our bases for objecting to each challenged exhibit. Based on the arguments developed by Anne, Justice Ramseur ordered most of the challenged exhibits to be excluded from evidence. Anne's hard work and skill has put our clients in a very good position. We are now writing our post-trial briefs - a process in which Anne is once again proving essential. Anne and I have spent dozens of hours working closely together in witness preps, strategy sessions, and at trial. She is unfailingly cheerful, a team player, a careful thinker, and a quick learner.

I can also speak to Anne's importance to the culture of Cooley's New York office. Anne is in the office rain or shine, while many other associates choose to work from home. Anne helps organize office social events, and was instrumental in coordinating an extremely memorable Thanksgiving potluck lunch for the department last November. And Anne is in constant demand to join fast-moving and complex litigation teams. While her departure for a clerkship would be well-deserved and any judge should be happy to have her, she will also be a loss to Cooley, and I hope she would consider returning quickly to Cooley after her clerkship.

I would be happy to speak live to answer any questions.

Respectfully submitted,

/s Nicholas Flath

48 W 87 St., Apt. #1B, New York, NY 10024 | bigleranne@gmail.com | (302) 824-8248

Introduction to Writing Sample

The following writing sample is a hypothetical memorandum of law in support of a motion to dismiss for a client who was named as a defendant in a *qui tam* False Claims Act action. The client is a former executive of a company accused by the Department of Justice ("DOJ") of defrauding Medicaid and Medicare by allegedly encouraging doctors to improperly "unbundle" Current Procedural Terminology ("CPT") codes to maximize reimbursement and to generally bill improperly. In the Spring of 2022, the DOJ sought and received court permission for a partial lift of the seal to notify our client that he had been named as a defendant in the suit. My team, which consisted of two partners and myself, engaged in a dialogue with the DOJ. This dialogue culminated in a presentation to the DOJ in January 2023. We were ultimately successful in persuading the DOJ not to intervene as to our client.

The below hypothetical memorandum of law reformats much of the research and fact development I did in preparation for the presentation into a brief. Names and entities have been replaced to protect the client's privacy.

This sample was reviewed by a partner on the matter with an eye towards privilege and confidentiality concerns. It was also proofed for typos and readability by a friend who is currently clerking in the District of Oregon.

48 W 87 St., Apt. #1B, New York, NY 10024 | bigleranne@gmail.com | (302) 824-8248

I. PRELIMINARY STATEMENT

With its Complaint, the Department of Justice (the "Government") stunts innovative medical technology. The Complaint fundamentally misunderstands the medical device at issue and contorts that misunderstanding into baseless allegations of Medicare and Medicaid fraud. This misunderstanding of the novel device is compounded by an absence of factual support to sufficiently plead the requisite elements of a False Claims Act ("FCA") violation by Ms. X. Together, these flaws are fatal to the Complaint, and it must be dismissed as to Ms. X.

In its Complaint, the Government relies on two theories to support its assertion that Ms. X "caused to be presented" false claims from doctors to Medicare and Medicaid: (i) that Ms. X enabled and encouraged improper "unbundling" of Current Procedural Terminology ("CPT") codes that resulted in overbilling for use of the E6 device and (ii) the underlying codes were themselves improper. Both theories are meritless. The Complaint fails to establish falsity, scienter, or causation on either theory. Accordingly, the Complaint must be dismissed.

First, with respect to the "unbundling" theory, this is in no way a traditional "unbundling" case where a doctor bills multiple codes for the same procedure. The E6 device runs six different brain- and heart-related procedures which are normally independently reimbursable with six separate CPT codes. The Complaint does not – and cannot – establish that the submitting of these otherwise legitimate codes became false claims merely by the fact that these procedures were run by the same device. Nor can they establish that Ms. X knew or should have known that this was the case.

Second, the Government's alternate theory that the codes themselves were improper also must fail. The Complaint presents no clear or consistent evidence that the codes being billed to Medicare or Medicaid were objectively false. Even more, as to Ms. X, whose role as Chief

48 W 87 St., Apt. #1B, New York, NY 10024 | bigleranne@gmail.com | (302) 824-8248 Scientific Officer has not been shown to have any billing responsibility, there are no facts plead to support the allegation that Ms. X knew or should have known that any or all of the CPT codes used by ABC Company ("ABC") in its marketing materials were inherently improper. Finally, this theory fails to consider the intervening determination by the medical professional who actually submitted the codes for reimbursement that the codes were proper as to a particular patient.

Thus, the facts alleged in the Complaint fail to state a claim under the FCA with respect to Ms. X, and the Complaint must be dismissed as to her.

II. <u>BACKGROUND</u>

Ms. X is the former Chief Scientific Officer ("CSO") and Chief Innovative Officer ("CIO") at ABC—a company founded upon the groundbreaking sciences of neurofeedback and biofeedback which use brain waves to target and treat brain injury and brain-based conditions like autism, depression, dementia, and Post Traumatic Stress Disorder ("PTSD"). Ms. X departed ABC in September 2019.

Ms. X and Ms. Y, ABC's Chief Executive Officer ("CEO"), established ABC in 2013. Shortly after, they created an amplifier device with an associated headset called the E6 device. The E6 device ran a series of independent procedures including electroencephalogram ("EEG") analyses when the patient was both awake and drowsy, an electrocardiogram ("ECG"), an assessment of auditory evoked potentials visual evoked potential, and general neuropsychological testing. The E6 device also had accompanying software which, by way of an algorithm, analyzed test results and provided them to doctors. The E6 device had the capability to run some but not all of the possible procedures. Doctors could deselect procedures that were not medically necessary for a given patient.

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Each of the six procedures performed by the E6 device has a corresponding CPT code. Soon after the creation of the device, ABC began incorporating these codes into its marketing materials. At all times that these codes appeared in ABC's marketing materials, they appeared with the disclaimer that these were codes that were *potentially* reimbursable depending on what was medically necessary for a given patient.

Around 2018, Ms. Y, in her capacity as CEO of ABC, engaged an outside consultant, LMO Reporting ("LMO"), to evaluate the CPT codes that ABC included in its marketing materials. LMO's conclusions stated that some but not all of the codes were proper. For example, LMO determined that CPT codes 12345 and 67891 were appropriate. LMO's report directed ABC to seek "additional societal or legal review" of the codes. LMO also flagged the existence of the "Not Otherwise Classified" ("NOC") CPT code but made no further recommendation about the use of that code.

Following the receipt of the report from LMO, Ms. Y, on behalf of ABC, engaged another reporting service, ERG Reporting ("ERG"), for a second opinion on the CPT codes.

ERG found that the code 67891, which LMO found to be appropriate, was improper. The ERG report made no mention of the NOC code but recommended that ABC seek additional guidance from Medicare and Medicaid directly because there was insufficient guidance on devices like the E6 device.

Although Ms. X was generally aware that LMO and ERG were retained, there is no allegation that Ms. X was involved in the reviews by LMO or ERG or privy to the findings of either reporting service prior to Ms. X's departure from ABC in 2019.

Just before Ms. X left in late 2019, AXIS, a group associated with Medicare and Medicaid that puts out local coverage determinations ("LCDs"), issued a determination that the

48 W 87 St., Apt. #1B, New York, NY 10024 | bigleranne@gmail.com | (302) 824-8248 E6 device should be billed only under the NOC code, and that it was not proper to bill the individual codes for the "panel of tests" run by the E6 device.

In the Spring of 2022, the Government intervened in this *qui tam* action, which named ABC, Ms. Y, and Ms. X as defendants. In this action, the Government alleges that all defendants "caused to be presented" false claims from doctors to Medicare and Medicaid by (i) encouraging improper "unbundling" of CPT codes that resulted in overbilling for use of the E6 device and (ii) encouraging the billing of improper CPT codes.

III. <u>LEGAL STANDARD</u>

A. MOTION TO DISMISS PURSUANT TO FRCP 9(B)

Where a complaint alleges fraud or mistake "a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. Pro. 9(b). The Third Circuit has held that complaints alleging violations of the FCA must meet this heightened pleading standard. Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 156-157 (3d. Cir. 2014). Indeed, a complaint is only sufficient where "a plaintiff [alleges] particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Id. To meet this burden, a complaint must allege in precise terms not only what was false and why, but also who specifically was involved and how they effectuated the exact conduct at issue. See U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC, 812 F.3d 294, 307 (3d Cir. 2016) (requiring "all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue").

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B. MOTION TO DISMISS PURSUANT TO FRCP 12(B)(6)

A court may dismiss action in whole or part for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). In considering such a dismissal, a court should view all factual allegations in a complaint in the light most favorable to the plaintiff. *See, e.g.*, *Dreibelbis v. Cnty. of Berks*, 438 F. Supp. 3d 304, 308 (E.D. Pa. 2020). However, to survive a motion to dismiss, a complaint cannot rely on unsupported legal conclusions. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("A pleading that offers 'labels and conclusions' or a 'formulaic recitation of the elements of a cause of action will not do"); *see also Dreibelbis*, 438 F. Supp. 3d at 308. ("[a] formulaic recitation of the elements of a cause of action" alone will not survive a motion to dismiss"). Indeed, a complaint can withstand a motion to dismiss "only where '[f]actual allegations...raise a right to relief above the speculative level' that [a] plaintiff has stated a plausible claim. *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d. Cir. 2008) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

Where a complaint incorporates outside documents by attaching or describing them, a court may consider those documents in its examination of the motion to dismiss. *Chester Cnty*. *Intermediate Unit v. Pa. Blue Shield*, 896 F.2d 808, 812 (3d Cir.1990).

C. ESTABLISHING A FALSE CLAIMS ACT VIOLATION UNDER 31 U.S.C. § 3729(A)(1)(A)

Under 31 U.S.C. § 3729(a)(1)(A), liability may be imposed upon any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the United States Government. Courts interpret § 3729(a)(1)(A) as requiring five distinct elements: (i) falsity; (ii) scienter; (iii) materiality; (iv) causation; and (v) damages. *U.S. ex rel. Petratos v. Genetech, Inc.*, 885 F.3d 481, 487 (3d Cir. 2017).

48 W 87 St., Apt. #1B, New York, NY 10024 | bigleranne@gmail.com | (302) 824-8248

IV. ARGUMENT

A. THE COMPLAINT DOES NOT PLEAD FRAUD WITH PARTICULARITY

In its Complaint, the Government does not "allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Foglia, 754 F.3d at 156-157. The Government's theory of the "scheme" appears to be that by generating marketing materials which included 6 CPT codes, one for each of the different procedures performed by the E6 device, ABC single-handedly caused doctors to bill inherently improper codes and to overbill Medicare and Medicaid. However, as outlined in more detail in the following pages, the Complaint is bereft of facts that show that the conduct was actually false, that Ms. X specifically would or should have known about any such alleged falsity, or how any alleged scheme perpetrated by ABC or Ms. X translated into independent doctors submitting purportedly false claims. In short, "the who, what, when, where, and how of the events at issue" are questionable at best, so the Complaint cannot survive. U.S. ex rel. Moore & Co., P.A., 812 F.3d at 307.

B. THE COMPLAINT DOES NOT PLEAD FALSITY

To make out falsity under the FCA, the Government must plead facts sufficient to show that the claim was factually or legally false. *U.S. ex rel. Jackson v. DePaul Health Sys.*, 454 F. Supp. 3d 481, 493-94 (E.D. Pa. 2020) (citing *U.S. ex rel. Wilkins v. United Health Grp., Inc.* 659 F.3d 295, 305 (3d Cir. 2011) (abrogated on other grounds). A claim is factually false where it "misrepresents what goods or services [were] provided to the government." *Id.* A legally false claim, however, involves misrepresentation by way of legal certification that a party has complied with "statutory, regulatory, or contractual requirement[s]." *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94 (3d Cir. 2018).

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The Complaint tries—and fails—to establish both legal and factual falsity in two ways. First, the Complaint asserts that CPT codes were improperly "unbundled" so as to fraudulently overbill Medicare and Medicaid. This first attempt to establish legal falsity fails on multiple grounds. The Complaint misapplies the term "unbundling" to an entirely new context where it has not yet been found to establish factual falsity. But, "unbundling" typically applies to efforts to break up, "or unbundle," multiple aspects of the *same procedure* for reimbursement. There is no objective guidance regarding – or precedent for treating as false or fraudulent – billing *multiple procedures* run by the same device. The Complaint's second theory of factual falsity, namely that the CPT codes themselves are improper, likewise fails as the guidance documents relied upon in support of this theory are inconsistent in their assessment of the propriety of the codes.

a. THE COMPLAINT MISCLASSIFIES THE CONDUCT AT ISSUE AS 'UNBUNDLING"

The Complaint seeks to maneuver past the motion to dismiss stage on falsity by employing old terminology for conduct well-established as false or fraudulent to describe an entirely new set of facts. "Unbundling" – or the practice of billing for all the component parts of a procedure rather than the single most comprehensive, "bundled" code for the entire procedure—often serves as the basis of FCA cases. *See, e.g., U.S. v. Metzinger*, 1996 WL 412811, at *1 (E.D. Pa. July 18, 1996) (denying a motion to dismiss FCA claims where the complaint alleged defendant billed component codes rather than composite code); *see also U.S. ex rel. Salters v. Am. Family Care, Inc.*, 262 F. Supp. 3d. 1266, 1284 (N.D. Ala. 2017).

The Complaint pleads no facts to support a legal falsity claim under any traditional definition of unbundling. Rather, the Complaint alleges only that doctor-users of the E6 device bill Medicare/Medicaid for each of the independent procedures performed by the E6 device. As pled, the mere fact that these otherwise independently reimbursable procedures were run by a

48 W 87 St., Apt. #1B, New York, NY 10024 | bigleranne@gmail.com | (302) 824-8248 single device renders them fraudulent and ineligible for reimbursement. The Complaint identifies no basis for its unprecedented expansion of the definition of unbundling to cover this new conduct.

b. THERE IS NO OBJECTIVE GUIDANCE THAT BILLING CODES FOR MULTIPLE PROCEDURES PERFORMED BY A SINGLE DEVICE IS UNBUNDLING

It is well established that, to properly plead the element of falsity under the FCA, a complaint must sufficiently show that the conduct at issue was *objectively* false. *See, e.g., U.S. ex rel.*Thomas v. Siemens AG, 593 Fed.Appx. 139, 143 (3d Cir. 2014) (for the purposes of the FCA, "[a] statement is 'false' when it is objectively untrue"); see also U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc, 525 F.3d 370, 376-77 (4th Cir. 2012) (citing U.S. ex rel. Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999) ("the statement or conduct alleged must represent an objective falsehood"). Indeed, "imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA." Id. Further, the Government may not treat noncompliance with a standard of practice announced solely in a guidance document as a violation of an applicable statute except as expressly authorized by law. Chesbrough v. VPA, PC., 655 F.3d 461, 466 (6th Cir. 2011) (finding that "agency guidance documents cannot create any additional legal obligations").

The Complaint pleads no *objectively* clear guidance on billing for the E6 device. To support its allegation that Ms. X and ABC company enabled false or fraudulent billing of CPT codes, the Government relies on two consultant reports commissioned by ABC and a local coverage determination ("LCD") published by AXIS, a group associated with Medicare and Medicaid. Together or apart, these reports cannot sustain a finding of falsity under the FCA.

The AXIS report does not establish objective falsity. First, the AXIS report fundamentally misunderstands the E6 device. The AXIS report asserts that, given the lack of precedent for

48 W 87 St., Apt. #1B, New York, NY 10024 | bigleranne@gmail.com | (302) 824-8248 similar technology, the E6 device should always be billed to the "Not Otherwise Classified" ("NOC") code. However, the LCD does not contemplate the ability of doctors to run some but not all of the tests able to be performed by the E6. For example, if the device was used to run only an EEG, which is an independently reimbursable code, the AXIS report provides no guidance on whether it is appropriate to bill to the EEG code, as would be done for any EEG not carried out by the E6 device, or if in that instance a doctor should still bill to the NOC code.

Next, the AXIS report is entirely inconsistent with the two consultant reports. Neither LMO nor ERG concluded that the NOC was the appropriate code for E6 device. LMO merely flagged the existence of the code and suggested seeking further societal or legal review, while ERG made no mention of the NOC code whatsoever. These inconsistencies between the AXIS and consulting group reports thwart any attempt by the Government to make a showing of objective falsity with respect to the supposed "unbundling."

c. THERE IS NO OBJECTIVE GUIDANCE THAT THE CODES WERE IMPROPER

The Government cannot establish that any of the CPT codes billed were factually false. Although AXIS, as described above, determined that none of the underlying codes were appropriate, both ERG and LMO approved of some of the codes. Even more, the consultant group reports not only differ dramatically from the AXIS report but are also inconsistent with each other. Indeed, LMO and ERG do not agree on which codes are appropriate. For example, LMO concludes that CPT code 67891 is appropriate, while ERG concludes 67891 is likely improper and directs ABC to conduct further investigation to determine if it is appropriate.

If the consultant reports show anything at all, it is that there was no clear guidance available at the time on how to bill for innovative devices like the E6. Indeed, LMO directed ABC to seek out additional review – which it did by hiring ERG. But more importantly, ERG concluded that

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Taken together, the combined guidance in the reports is confused, contradictory, and at best ambiguous. Thus, the Government's allegations are insufficient to establish objective falsity, so the Complaint must be dismissed.

C. THE COMPLAINT DOES NOT PLEAD THE MINIMUM MENTAL STATE OF RECKLESSNESS

In addition to failing to plead falsity, the Complaint similarly fails to allege sufficient facts to properly plead scienter on behalf of Ms. X. To establish scienter under the FCA, the Government must establish that Ms. X "knowingly" caused false claims to be submitted. Knowingly" under the FCA requires that Ms. X: (i) had actual knowledge of the information; (ii) acted in deliberate ignorance of the truth or falsity of the information; or (iii) acted in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729 (b)(1)(A). A plaintiff cannot establish scienter by pooling together mental states of different employees. *U.S. ex rel. Int'l Bhd. of Elec. Workers Loc. Union No. 98 v. Fairfield Co.*, 438 F. Supp.3d 348, 380 (E.D. Pa. 2020) (citing *U.S. v. Fadul*, 2013 WL 781614, at *9 (D. Md. Feb 28, 2013) (rejecting an attempt by the Government to "'pool together the collective knowledge' of defendant's employees to establish it acted with actual knowledge or reckless disregard.")

The facts alleged in the Complaint do not properly plead even recklessness, the minimum mental state, as to Ms. X. Even assuming that there was clear billing guidance – which there was not – the Complaint still alleges no facts to support the conclusion that Ms. X actually knew that codes were themselves improper or were being billed improperly. Further, none of the facts alleged in the Complaint establish that by nature of her position or professional training, Ms. X should have known that either the codes were inherently improper or that billing multiple codes

48 W 87 St., Apt. #1B, New York, NY 10024 | bigleranne@gmail.com | (302) 824-8248 for the multiple procedures run by the device would constitute improper unbundling. There is no suggestion that Ms. X, as Chief Scientific Officer, had any responsibility for advising on or overseeing anything related to billing or reimbursement guidelines or marketing material creation. And, there is no allegation that Ms. X ever saw any of the final consultant reports or the AXIS LCD before she departed the company. While the Complaint does make such allegations against Ms. Y, any such billing responsibility or knowledge of Ms. Y cannot be "pooled" and made to apply to Ms. X. As such, the Complaint does not establish that Ms. X was reckless, and, therefore, it cannot survive as to her.

D. THE COMPLAINT DOES NOT PLEAD CAUSATION

The Complaint makes no real attempt to properly plead causation. In order to satisfy the causation element of the FCA, "there must be some level of direct involvement in causing the submission of false claims to the Government." *U.S. ex rel. Ellsworth Assoc., LLP v. CVS Health Corp.*, 2023 WL 2467170, at *14 (internal quotations and citation omitted). A plaintiff cannot simply describe causation in the abstract. Rather, he "must link that scheme to a particular claim submitted to the government for payment." *U.S. ex rel. Gohil v. Sanofi U.S. Services Inc.*, 500 F.Supp.3d 345, 360 (E.D. Pa. 2020) (internal quotations and citation omitted). Here, to sufficiently plead the element of causation, the Government must establish that the marketing materials proximately caused false claims to be submitted. *See U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 491 (3rd Cir. 2017). Simple "but-for" causation is not sufficient. *Id.* (citing *U.S. ex rel. Hendow v. Univ. of Phoenix*, 461F.3d 116, 1174 (9th Cir. 2006) (a false claim must be "*integral* to a causal chain leading to payment"); *see also U.S. v. Kindred Healthcare, Inc.*, 469 F. Supp. 3d 431, 444 (E.D. Pa. 2020) (for a third party to be found liable under the FCA, its conduct must be a "substantial factor in bringing about" the false claims).

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The Complaint fails to allege sufficient facts to properly plead causation. The entirety of the Complaint's case for causation rests on marketing materials generated by ABC. But, the Complaint makes no real attempt to link the ABC marketing materials to the specific doctors who submitted the allegedly false claims. The Complaint alleges no facts to establish the doctors who actually submitted the allegedly false claims ever actually saw ABC's marketing materials, much less relied on them in submitting codes for reimbursement. Rather, the Complaint impermissibly describes an abstract scheme by which ABC encouraged doctors to overbill and bill inappropriate codes based on nothing but the fact that these marketing materials existed. Even more, the face of the marketing materials relied upon by the Government clearly and repeatedly provide the disclaimer that the identified codes "may" be reimbursable but that independent doctor determinations of medical necessity in particular patients are required. Relatedly, the Complaint fails to contemplate the existence of an intervening cause in the form of doctor's independent medical judgment. What a doctor determines to be medically necessary and what he ultimately bills for are independent medical decisions. As such, there is no serious or substantiated allegation of "direct involvement" by ABC in the submission of codes for reimbursement that would permit the Complaint to survive on the element of causation.

CONCLUSION

For the foregoing reasons, Ms. X respectfully requests that this Court grant her motion to dismiss with prejudice.